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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

VASAT, PETER S

ART UNIT

PAPER NUMBER

3764

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/583,878	Applicant(s) GENOSAR, AMIR	
	Examiner PETER S. VASAT	Art Unit 3764	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-25 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-25 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 21 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3, 9-12, 14-17, 21, 23, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Poss (US 5347999).

a. In re claim 1, Poss discloses an inhalation device having a supply of solidified medicinal substance to be inhaled, a manually operable metering device for removing a given dose of the powdered medicinal substance for the inhalation process and having a mouthpiece 16 connected to an air outlet 99 from the flow chamber 24 (air space) for distributing the particular dose of powdered medicinal substance in the air stream (abstract; col. 2, ll. 19-23; col. 3, ll. 33-36). Poss further discloses that the inhalation device has at least one air inlet 20 (col. 2, ll. 19-23). Additionally, Poss discloses that the flow chamber 24 contains a compressed powder volume 4 and at least one scraping surface 5 (col. 2, ll. 24-32; fig. 1). When the user inhales from the mouthpiece 16 connected to the air outlet, the air flows in from at least one air inlet 20 through the flow chamber 24 with the air flow thereby generating motion between the scraping surface 5 and the compressed powder volume 4 such that fine particles

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of powder are scraped from the compressed powder volume 4 and inhaled by the user through the mouthpiece (col. 3, ll. 11-32).

b. In re claim 3, Poss discloses the invention as discussed above in claim 1, and further discloses that the inhalation device can be used with multiple separate compressed powder volumes 4 that are advanced into the chamber to reload the device (col. 4, ll. 8-14).

c. In re claim 9, Poss discloses the invention as discussed above in claim 1, and further discloses that during a mode of operation the scraping surfaces are movable and said compressed-powder volumes are static (col. 2, ll. 30-32).

d. In re claim 10, Poss discloses the invention as discussed above in claim 1, and further discloses that during a mode of operation the scraping surfaces are static and said compressed-powder volumes are movable (col. 2, ll. 1-6).

e. In re claim 11, Poss discloses the invention as discussed above in claim 1, and further discloses that both scraping surfaces and said compressed-powder volumes are movable (col. 2, ll. 30-32; col. 2, ll. 1-6).

f. In re claim 12, Poss discloses the invention as discussed above in claim 9, and further discloses that the movement is synchronized with the inhalation flow, as discussed above in claim 1.

g. In re claim 14, Poss discloses the invention as discussed above in claim 1, and further discloses a device that is shaped like a cylinder or a conventional hand-held inhaler (fig. 1).

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- h. In re claim 15, Poss discloses the invention as discussed above in claim 1, and further discloses that the compressed powder volume is a tablet (col. 2, ll. 30-32).
- i. In re claim 16, Poss discloses the invention as discussed above in claim 15, and further discloses that the drug is fixed to a member 1 which is introduced to the flow control chamber (col. 2, ll. 30-39).
- j. In re claim 17, Poss discloses the invention as discussed above in claim 16, and further discloses that the drug is protected in an enclosure (cap) that is opened prior to use (col. 3, ll. 37-45).
- k. In re claim 21, Poss discloses the invention as discussed above in claim 16, and further discloses that the compressed-powder volume 4 is replaceable (col. 4, ll. 14).
- l. In re claim 23, Poss discloses the invention as discussed above in claim 1, and further discloses a multiplicity of air inlets 20 (col. 4, ll. 1-7).
- m. In re claim 25, Poss discloses the invention as discussed above in claim 1, and further discloses a multiplicity of scraping surfaces 5 (fig. 3).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 2, 4, 19-20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poss (US 5347999) in view of Clark (US 5628307).

n. In re claim 2, Poss discloses the invention as discussed above in claim 1.

As discussed above, Poss discloses that the inhalation of the user generates the abrasive motion between the compressed powder volume 4 and the scraping surface 5. Therefore, a time lag must exist between the start of the inhalation and the first release of particles, because some time would pass before the proper pressure drop within the flow chamber 24 would occur. However, Poss does not disclose that the scraping surface is a blade of an impeller, said blade gradually extending outwards as said impeller rotates. Clark teaches a device for the administration by inhalation of a medicament in powdered form comprises a medicament reservoir 3 and metering means for dispensing a dose of medicament from the reservoir 3, characterized in that the reservoir 3 comprises a compacted body of powdered medicament 10 and the metering means includes means 11 for abrading the compacted body 10 (abstract). Clark further teaches that variations in the density of the metered powder resulting in

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inaccurate or inconsistent dosing (col. 1, ll. 35-37) can be substantially mitigated by the use of a metering means which relies not on gravitational force to fill a metering chamber, but on abrasion of a compacted body of powdered medicament (col. 1-2, ll. 66-3). Clark further teaches a bladed impeller that gradually extends outward from the inhaler as the impeller rotates (fig. 3-4; col. 3, ll. 11-19). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Poss with the bladed impeller that gradually extends outward as the impeller rotates, as taught by Clark, to substantially mitigate variations in the density of a metered powder by the use of a metering means which relies not on gravitational force to fill a metering chamber, but on abrasion of a compacted body of powdered medicament.

o. In re claim 4, Poss discloses the invention as discussed above in claim 1, but does not disclose a particle filter located between said flow chamber and said outlet to ensure that large particles are not inhaled. Clark further teaches that grids through which air and entrained powdered medicament pass can be provided between the flow chamber and the outlet to improve the quality of the medicament cloud (col. 3, ll. 64-67). A grid would be an effective particle size filter that ensures that overly large particles are not inhaled. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Poss with the particle filter located between said flow chamber and said outlet to ensure that large particles are not inhaled, as taught by Clark, to improve the quality of the medicament cloud.

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p. In re claim 19, Poss discloses the invention as discussed above in claim 1, but does not disclose that the compressed-powder volume is compressed into a structural element. Clark teaches a tightly compacted body of medicament may be obtained by applying pressure, the degree of compaction would be sufficient for such bodies to retain their structural integrity upon handling (col. 2, 28-34).

Therefore, Clark teaches a compressed-powder volume that is compressed into a structural element. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Poss with the compressed-powder volume compressed into a structural element, as taught by Clark, to provide a compressed-powder volume that retains its structural integrity upon handling.

q. In re claim 20, Poss discloses the invention as discussed above in claim 1, but does not disclose that the device is loaded with more than one drug. Clark teaches that the device may be loaded with more than one drug (col. 2, ll. 55-60). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Poss with the addition of more than one drug, as taught by Clark, to provide a combination treatment.

r. In re claim 22, Poss discloses the invention as discussed above in claim 1, but does not disclose that the scraping means belongs to the group including impellers and fixed internal surfaces of said device. As discussed above in claim 2, Poss in view of Clark disclose an impeller scraping means.

6. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poss (US 5347999) in view of Lerk (5301666).

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s. In re claim 5, Poss discloses the invention as discussed above in claim 1, but does not disclose a mouthpiece attachable to said outlet. Lerk teaches a powder inhaler that features a disposable cylinder 55 composed of parts 1, 2, 3, 4, 5 and 6, a guide cylinder 7, an outer cylinder 8 which includes an inhaler base 9 and a mouthpiece 10, 11, 29 (col. 3, ll. 62-68; fig. 1). The powder inhaler can be dismantled into these parts for cleaning and refilling (col. 3, ll. 62-68; fig. 1). Therefore, the mouthpiece taught by Lerk is attachable and detachable to the outlet. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Poss with a mouthpiece attachable to said outlet, as taught by Lerk, to allow for efficient cleaning and refilling.

t. In re claim 6, Poss in view of Lerk disclose the invention as discussed above in claim 5, and Poss further discloses a mouthpiece 16 that integral to the inhaler, as shown in figure 1.

u. In re claim 7, Poss in view of Lerk disclose the invention as discussed above in claim 5. The attachable mouthpiece taught by Lerk would be attached by the patient or other user to the outlet after refilling or cleaning.

7. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Poss (US 5347999) in view of Lerk (5301666), and further in view of Rand (US 6748946).

v. In re claim 8, Poss in view of Lerk disclose the invention as discussed above in claim 5, but they do not disclose a storage compartment for said mouthpiece. Rand teaches a inhaler that features a mouthpiece 90 and a storage compartment for the mouthpiece 90, as shown in figures 2a and 2b (col.

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2, ll. 39-44). Rand's storage compartment avoids contamination problems (col. 1, ll. 59-60). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Poss in view of Lerk with the storage compartment for a mouthpiece taught by Rand to avoid contamination problems.

8. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Poss (US 5347999) in view of Hurka (US 4841964).

w. In re claim 13, Poss discloses the invention as discussed above in claim 1, but does not disclose that the device is shaped like a credit-card. Hurka teaches a powder inhaler that is shaped like a credit card (fig. 13). Hurka further teaches that the design of the inhaler allows production in a very small size, so that the inhaler may conveniently be carried by a user at any time (col. 3, ll. 8-10). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Poss with the shape taught by Hurka to provide an inhaler in a very small size, so that the inhaler may conveniently be carried by a user at any time.

9. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Poss (US 5347999) in view of Heide (US 6054082).

x. In re claim 18, Poss discloses the invention as discussed above in claim 1, but does not disclose that the active drug ingredients are selectively dispersed in the compressed-powder volume. Heide teaches selectively dispersed active drug ingredients in a compressed powder volume to provide desired particle uniformity (col. 2, ll. 45-51). It would have been obvious to one of ordinary skill in

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the art at the time the invention was made to modify Poss with the selectively dispersed active drug ingredients taught by Heide to provide desired particle uniformity.

10. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Poss (US 5347999) in view of Mulhauser (US 5388572).

y. In re claim 24, Poss discloses the invention as discussed above in claim 1, but does not disclose a multiplicity of compressed-powder volumes. Mulhauser teaches a dry powder inhaler featuring a multiplicity of compressed-powder volumes 16 (fig. 4; col. 6, ll. 26-39). Mulhauser's invention enables a predetermined exact dose to be supplied through an inhalator with the ingested particle size of the powdered dose being formed for maximum beneficial efficiency (col. 3, ll. 26-30). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Poss with the multiplicity of compressed-powder volumes taught by Mulhauser to enable a predetermined exact dose to be supplied through an inhalator with the ingested particle size of the powdered dose being formed for maximum beneficial efficiency.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PETER S. VASAT whose telephone number is (571)270-7625. The examiner can normally be reached on Monday - Thursday, 8:00AM - 6:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LoAn Thanh can be reached on (571)272-4966. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/PETER S. VASAT/
Examiner, Art Unit 3764

/LoAn H. Thanh/
Supervisory Patent Examiner, Art Unit 3764